



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Eoh

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/222,443 12/29/98 YANG

HM22/0503

JOHN W RYAN
IGEN INC
16020 INDUSTRIAL DRIVE
GAITHERSBURG MD 20877

H	17100
EXAMINER	

ART UNIT	PAPER NUMBER
----------	--------------

DATE MAILED:

05/03/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/222,443

Applicant(s)
YANG et al

Examiner
Mary E. Cep rley

Group Art Unit
1641



☒ Responsive to communication(s) filed on Apr 20, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 21-23 is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 21-23 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 1641

1. Claims 21-23 are again rejected under 35 USC 112, first and second paragraphs, for the reasons of record. In light of the amendment to the claims which defines the term “a chemical moiety” by specific structure, these rejections have been overcome for the term “a chemical moiety”; however, the rejections are maintained with regard to the remaining terms which were addressed in the first Office action.

Applicant's arguments filed April 20, 2000 have been fully considered but they are not persuasive. Although applicant argues that the terms “assay reagent composition”, “system”, “a reagent mixture” and “an agent” are supported in the specification there is *no actual description in the specification* to support these terms. A “system” is described at page 26 of the specification, but this “system” includes a) the chemical moiety, b) a means for contacting the chemical moiety with the analyte, c) a means for inducing the emission of electromagnetic radiation and d) a means for detecting the electromagnetic radiation. The “system” does not include the “agent” of (a) of claims 21-23. Pages 24 and 25 of the specification further describe exposure of the “chemical moiety” to an electrode and the use of specific reagents (e.g. oxalate, pyruvate, lactate, etc. and acetonitrile or peroxydisulfate) in combination with the “chemical moiety”. However, these descriptions *include neither the terms in question nor a generic description of them.*

2. Claims 21-23 are again rejected under the judicially created doctrine of obviousness-type double patenting as being obvious over the claims of U.S. Patent No. 5,858,676 for the reasons of

Art Unit: 1641

record. Applicant's request that this rejection be held in abeyance pending the determination of allowable subject matter is acknowledged.

3. Claims 21-23 are again rejected under 35 U.S.C. 102(b)/(e) as being anticipated by each of Kankare, Bard et al, or Weber for the reasons of record.

Applicant has not specifically described how the "compositions" and "systems" of the instant claims differ from each of the cited references (see the citations to specific sections of the references set forth in the first Office action). The following points are further noted: both the compound of claim 2 of Kankare et al and the structure of claim 1 of Bard et al meet the definition of the "chemical moiety" of instant claim 21; the labeled analyte of Weber wherein the label is either a Co or a Ru complex (see col. 8, Preparation of ruthenium complex Labeled Analyte) anticipates the "chemical moiety" of instant claim 21. Since the "chemical moieties" of the prior art are the same as those of the instant claims, the "chemical moieties" of the prior art would inherently have the characteristics described in (b) (I) and (b)(ii) of instant claim 21.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

Art Unit: 1641


the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. (Molly) Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

mec
c:\docs\actions\222443.fr
May 02,2000
Disk: 03/00


Mary E. Ceperley
Primary Examiner
Art Unit 1641